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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Jonathan Stinson
Application No.:	10/037036
Filed:	October 25, 2001
For:	Balloon Expandable Polymer Stent With Reduced Elastic Recoil
Examiner:	Vi X Nguyen
Group Art Unit:	3734
Firm Docket No.:	S63.2B-9919-US01

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Respectfully submitted,
VIDAS, ARRETT & STEINKRAUS

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P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2B-9919-US01

APPEAL BRIEF

This is an Appeal Brief for the above-identified application in which pending claims 1 – 11, 15 – 24, and 26 – 32 were rejected in the Final Office Action dated July 13, 2007.

A Notice of Appeal was filed in this case on September 12, 2007.

This is a second appeal in this application so this brief is being filed with a reduced fee payment.

The Commissioner is authorized to charge Deposit Account No. 22-0350 for any other fees which may be due with this Appeal Brief.

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(i) Real Party in Interest

The Application is assigned to Boston Scientific Scimed, Inc., formerly known as Scimed Life Systems, Inc., One SciMed Place, Maple Grove, Minnesota 55311-1566, a Minnesota corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

No related interferences or Appeals are currently pending. However in this application an Appeal was taken from a prior rejection, Notice of Appeal filed 12/20/2004; Appeal Brief filed 2/16/2005 (PAIR dates). The previously appealed rejection was withdrawn in an Office Action mailed 3/3/2006.

(iii) Status of the Claims

Claims 1-32 have been presented in the application. Claims 12 – 14 were canceled in an amendment filed August 1, 2006. Claim 25 was canceled in an amendment filed November 15, 2006. Claims 1-11, 15-24 and 26-32 are currently pending.

Claims 1 – 11, 15 – 24, and 26 – 32 were finally rejected in an Office Action mailed July 13, 2007 and are the subject of this Appeal.

(iv) Status of Amendments

No amendments have been filed after the Final Rejection dated July 13, 2007.

(v) Summary of Claimed Subject Matter

A summary of the independent claims, as required by 37 C.F.R. § 41.37(c)(1)(v), and a non-limiting listing of locations where support may be found [bracketed citations] is provided as follows:

Claim 1 is directed toward a process comprising steps "a" – "c". Step "a" includes forming a generally tubular stent [page 5, lines 4 – 9] of polymer material [page 6, lines 3 – 15]. Step "b" includes radially expanding the stent to produce an expanded diameter stent. [Page 5, lines 10 – 20]. Step "c" includes annealing the expanded diameter stent to shrink its diameter to a reduced diameter. [Page 5, lines 21 – 27]. Steps "a" – "c" are all performed prior to deployment of the stent in a body. [Page 10, lines 18-22].

Claim 15 is directed toward a process comprising steps "a" – "c". Step "a" includes forming a generally tubular article [page 5, lines 4 – 9; page 12, lines 6 – 9] of polymeric material [page 6, lines 3 – 15]. Step "b" includes radially expanding the article to produce an expanded diameter article. [Page 5, lines 10 – 20]. Step "c" includes annealing the expanded diameter article to shrink its diameter to a reduced diameter. [Page 5, lines 21 – 27]. Steps "a" – "c" are all performed prior to deployment of the tubular article in a body. [Page 10, lines 18-22]. And, at least one time steps "b" and "c" are repeated in sequence on the tubular article. [Page 5, lines 25 – 27].

Claim 17 is directed toward a process comprising steps "a" – "c". Step "a" includes forming a generally tubular article [page 5, lines 4 – 9; page 12, lines 6 – 9] of polymeric material [page 6, lines 3 – 15]. Step "b" includes radially expanding the article to produce an expanded diameter article. [Page 5, lines 10 – 20]. Step "c" includes annealing the expanded diameter article to shrink its diameter to a reduced diameter. [Page 5, lines 21 – 27].

Steps "a" – "c" are all performed prior to deployment of the tubular article in a body. [Page 10, lines 18-22]. The polymer material is a biodegradable polymer. [Original claim 17; page 6, line 3 – page 7, line 2]

Claim 21 is directed toward a process comprising steps "a" – "d". Step "a" includes forming a tube [page 5, lines 4 – 9; page 12, lines 6 – 9] of polymeric material [page 6, lines 3 – 15]. Step "b" includes radially expanding the tube to produce an expanded diameter tube. [Page 5, lines 10 – 20; page 12, lines 6 – 9]. Step "c" includes annealing the expanded diameter tube to shrink its diameter to a reduced diameter. [Page 5, lines 21 – 27; page 12, lines 6 – 9]. Step "d" includes forming a stent from the annealed tube. [Page 12, lines 6 – 9] Steps "a" – "d" are all performed prior to deployment of the stent in a body. [Page 10, lines 18-22].

Claim 26 is directed toward a process comprising steps "a" – "d". Step "a" includes forming a generally tubular article. [Page 5, lines 4 – 9; page 12, lines 6 – 9]. Step "b" includes radially expanding the tubular article to produce an expanded diameter tubular article. [Page 5, lines 10 – 20]. Step "c" includes annealing the expanded diameter tubular article to shrink its diameter to a reduced diameter. [Page 5, lines 21 – 27]. Step "d" includes forming the tubular article as a stent with a pattern of perforations therein. [Page 12, lines 6 – 9].

(vi) Grounds of Rejection to be Reviewed on Appeal

I. Whether the Examiner erred in rejecting claims 1 – 11, 15 – 24, and 26 – 32 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,670,161 to Healy et al. (hereafter "Healy") in view of U.S. Patent No. 5,868,783 to Tower (hereafter "Tower").

(vii) Arguments

The Examiner erred in rejecting claims 1 – 11, 15 – 24, and 26 – 32 under 35 U.S.C. § 103 over Healy in view of Tower.

The invention provides novel techniques by which the molecular orientation of a formed stent or a tubular stent preform can be improved to increase hoop-wise orientation. The process is particularly suited to balloon expandable polymer stents. Such stents typically have suffered from high elastic recoil after release of balloon inflation pressure [p. 4, lns. 14-23]. The processes of all the independent claims involve radial expansion of a tubular article or formed stent and annealing of the expanded diameter article to shrink its diameter.

The purpose of the radial expansion step is to cause the molecular structure of the polymer to orient itself around the hoop, stretching causing molecular alignment in the direction of the elongation and increasing strength in the direction of orientation [p.8, ln.22-29]. The purpose of the annealing/shrinking step is to reduce or eliminate residual elastic stresses and to shrink the stent to size for deployment [p.9, ln.15-21].

The combined teachings of these documents do not meet the recitations of any of the claims. None of the rationales to support a rejection articulated in the USPTO "Examination Guidelines for Determining Obviousness under 35 USC 103 in view of the Supreme Court Decision in KSR International Co. v. Teleflex Inc." 72 Fed. Reg. 57526, 57528-29, are applicable to the instant rejection. Consequently the invention is not obvious.

A. Claims 1 - 11, 15 - 24 and 26 - 32 - Annealing an Expanded Tubular Article or Stent

All of the independent claims recite an annealing step performed on an expanded diameter tubular article or stent to shrink its diameter to a reduced diameter. Neither the Healy

nor Tower patents teach such a step.

The stents of Healy are formed in the configuration for delivery (col. 8, line 66-col. 9, line 3). The stents may be formed in a number of ways (*see e.g.* col 8, lines 49-65 and col. 9 lines 17- 65). None involve annealing to shrink the stent diameter.

Healy's stents are heated at the time of expansion (*see* col. 3, lines 39-45 and col. 10. line 66 - col. 11, line 3, and col. 11, lines 32-51). The heating allows the polymer material to plastically deform so that it retains its expanded configuration when cooled (*see* col. 7, lines 50-61 where Healy teaches that following the heated expansion the stent is cooled and "remains open"). The stents are heated and expanded when the stent is deployed in the body (col. 8, lines 5-7).

Annealing is mentioned at col. 10, lines 62-65 of Healy, but this disclosure pertains to the stents as formed, not to annealing expanded diameter stents. Furthermore, there is no indication that the stent diameter is shrunk when annealed. Annealing can be done on a mandrel, so diameter shrinking is clearly not necessarily inherent in Healy's context. In the Final Action the Examiner acknowledges that "Healy is silent regarding the step of annealing the expanded diameter stent or tubular article to shrink its diameter to a reduced diameter."

Regarding the combination of Healy with Tower, the Examiner is clearly mistaken in asserting that "Tower teaches annealing the expanded diameter stent ... to shrink its diameter to a reduced diameter ..." The cited passage of Tower pertaining to annealing (*i.e.* col. 3, lines 60-67 and col. 4, lines 1-7) describes annealing a malleable metal wire "prior to forming ... The wire before bending, *being in the fully annealed condition*, will retain whatever shape it is firmed [*sic*] into" (emphasis added). The annealing therefore is performed prior to formation of the wire into a stent configuration. This passage of the Tower patent therefore has nothing to do with

annealing a stent or a tube. Still further, the passages of Tower asserted in the Office Action to pertain to stent diameter shrinkage (*i.e.* abstract, and col. 5, lines 31-39) actually pertains to the "axial" or "lateral" shrinkage which the stent undergoes during radial expansion (*i.e. diameter expansion*). These passages have nothing whatsoever to do with shrinkage of a stent, or tubular article, to a reduced diameter by annealing. The combination of Tower and Healy, therefore, does not meet the recitations of any of the rejected claims.

At least for this reason, all of the rejected claims are seen to be both novel and non-obvious over the cited documents. Reversal of the rejection of 1 - 11, 15 - 24 and 26 - 32 for obviousness from Healy in view of Tower is respectfully requested.

B. Claims 1 – 11, and 15 – 24 - Prior to Deployment in the Body

According to independent claims 1, 15, 17 and 21 the recited steps are "all performed prior to deployment in the body."

The Final Office Action asserts:

> Healy discloses in fig 5, a process for forming a stent having the limitations of claims 1- 23, including: the process comprises the step of forming a tubular stent of the polymer material (see col. 9, lines 22-46); the stent radially expanding to produce an expanded diameter stent (see col. 3, lines 9-45), and at least one time repeating of steps a-b are all performed prior to deployment of the stent in a body (see col. 7, lines 50-67), but Healy is silent regarding the step of annealing the expanded diameter stent or tubular article to shrink its diameter to a reduced diameter.

The applicant does not agree. As discussed above, it is true that Healy fails to disclose annealing an expanded diameter stent or tubular article to shrink its diameter to a reduced diameter. However it is *not true* that Healy otherwise discloses a process having the limitations of claims 1 – 23. Relevant to these particular claims, Healy's stents also are not radially expanded ***prior to***

stent delivery.

The Examiner cites col. 7, lines 50-67 apparently for the assertion that Healy teaches expansion prior to delivery. The full text of this paragraph, which continues to col. 8, line 4, is reproduced below.

> Using the heating techniques described more fully below, the temperature of the polymer can be increased incrementally to a point near the glass-transition temperature of the copolymer, permitting the stent to enter a rubbery phase that takes advantage of a lower elastic modulus. In this phase, the stent may be plastically deformed and the shape stabilized prior to any viscoelastic behavior (such as creep, stress relaxation, strain recovery, or shrinkage) causes the stent to return to its unexpanded shape or to diminish in strength. ***Following expansion,*** the polymer is allowed to cool, but because plastic deformation has occurred, ***the stent remains open.*** Attempting to expand the stent of the present invention below the glass-transition temperature causes the stent to fracture as a result of its brittle or glassy characteristics below the glass-transition temperature. This could be potentially hazardous, depending upon whether and how the stent fractures as a result of being expanded improperly. Thus, controlled heating and expansion of the stent is important to the invention, as it results in a circumferential drawing of the extruded stent, helping to orient the copolymer molecules, and thereby enhances the modulus and strength of the materials, and ultimately the strength of the stent.
>
> (emphasis added)

The Examiner has clearly misunderstood the paragraph. Nothing in this paragraph indicates that it is speaking of the stent prior to deployment. To the contrary, the "remains open" teaching would prevent delivery of the Healy stent if it occurred prior to the time the stent is deployed.

Furthermore the Examiner has ignored the critical context statement which is found in the first sentence of the next paragraph:

> ***The thermo-mechanical expansion of the stent*** is considered a processing step ***occurring in situ and concomitant with deployment.***
>
> (col. 8, lines 5-7, emphasis added)

That is, the thermo-expansion step described at col. 7, lines 50 - col. 8 line 4, is expressly taught as one that is performed <u>in body</u> at the time of deployment, <u>not prior to deployment</u> as recited in claims 1 – 11 and 15 – 24. Thus the only description in Healy of expanding the stents to an expanded diameter is in the context of expansion <u>at the site of deployment</u>.

At least for the additional reasons given above reversal of the rejection of 1 - 11 and 15 - 24, for obviousness from Healy in view of Tower is respectfully requested.

C. Claims 2, 15-16, 18, 22, 29 - Repetition

These claims recite repetition of the radial expansion and annealing/shrinking steps at least once. The repetition is performed on the same antecedent article and, as such, is not met merely by performing the same steps once on a plurality of different stents or tubes.

To the extent that the Examiner has cited col. 7, lines col. 7, lines 50-67 as showing repetition of "steps a – b," it seems that the Examiner has misunderstood the relevant repetition recitations in these claims. Repetition of a step a) is not recited in any claim. Further there is no teaching in Healy or Tower that can be reasonably construed as suggesting repetitive expansion and shrinking of the same stent or tube.

Still further, the application (page 9, lines 22-25) teaches that multiple expansions and annealings performed on the *same* tubular article can provide cumulatively increased radial orientation of the polymer material. This is a novel and non-obvious benefit not hinted at by anything in Healy or in Tower.

At least for these additional reasons reversal of the obviousness rejection of claims 2, 15-16, 18, 22, and 19 from Healy in view of Tower is respectfully requested.

D. Claims 8, 9 and 31 - Radial Expansion below Glass Transition Temperature

Claims 8 and 31 recite that the radial expansion step is performed at a temperature below the glass transition temperature of the polymer material. Claim 9 depends from claim 8.

The above quoted portion of the Healy patent (col. 7, line 50- col. 8, line 4) clearly

and unambiguously teaches that the stent is to reach "a rubbery phase," at the time of expansion. This is the characteristic of polymer material at or above its glass transition temperature. Healy also teaches that "[a]ttempting to expand the stent of the present invention below the glass-transition temperature causes the stent to fracture as a result of its brittle or glassy characteristics below the glass-transition temperature." No one would want this consequence. Consequently Healy clearly is ***teaching away*** from radially expanding the stent below the glass-transition temperature. Taken together these statements clearly teach the skilled person that Healy's "near the glass-transition temperature" only pertains to temperatures that are actually *at or above* the glass transition temperature of the material. Healy's expansion step therefore does not meet the recitations of claims 8, 9 or 31.

At least for this additional reason reversal of the obviousness rejection of claims 8, 9 and 31 from Healy in view of Tower is respectfully requested.

E. Claim 9 - Radial Expansion at Room Temperature

Claim 9 depends from claim 8 and further specifies the temperature of the radial expansion step as room temperature. This cannot reasonably be argued to be near the glass transition temperature for any of Healy's stent materials. At least for this additional reason reversal of the obviousness rejection of claim 9 Healy in view of Tower is respectfully requested.

Conclusion

For at least the reasons presented above, claims 1 – 11, 15 – 24, and 26 – 32 are non-obvious over the cited art. Consequently, reversal of the rejections is respectfully requested.

Respectfully submitted,
VIDAS, ARRETT & STEINKRAUS

Date: November 12, 2007

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(viii) Claims Appendix

Claim 1. A process comprising the steps of:

a) forming a generally tubular stent of polymer material;

b) radially expanding the stent to produce an expanded diameter stent; and then,

c) annealing the expanded diameter stent to shrink its diameter to a reduced diameter,

wherein the steps a) - c) are all performed prior to deployment of the stent in a body.

Claim 2. A process as in claim 1 further comprising at least one time repeating steps b) and c) in sequence on said stent.

Claim 3. A process as in claim 1 wherein in step a) the stent is formed by molding the polymer material.

Claim 4. A process as in claim 3 wherein the polymer material is thermoplastic.

Claim 5. A process as in claim 4 wherein the polymer material is biodegradable.

Claim 6. A process as in claim 1 wherein the polymer material is selected from the group consisting of poly(alpha-hydroxy acid), polylactic acid-polyethylene oxide copolymers; modified cellulose; collagen or other connective proteins; adhesive proteins; hyaluronic acid; polyanhydrides; polyphosphoesters; poly(amino acids); copolymers thereof; and mixtures of any of said materials.

Claim 7. A process as in claim 6 wherein the polymer material is a poly(alpha-hydroxy acid) selected from the group consisting of homopolymers and copolymers of polylactide (PLA), poly-L-lactide (PLLA), poly-D-lactide (PDLA), polyglycolide (PGA), polydioxanone, polycaprolactone, poly(hydroxybutyrate), polygluconate, and mixtures thereof.

Claim 8. A process as in claim 1 wherein the step b) is performed at a temperature below the glass transition temperature of the polymer material.

Claim 9. A process as in claim 8 wherein the step b) is performed at room temperature.

Claim 10. A process as in claim 1 wherein the step c) is performed at a temperature above the glass transition temperature of the polymer material.

Claim 11. A process as in claim 10 wherein the step c) is performed at a temperature within the range of about 90°C to about 150°C.

Claim 15. A process comprising the steps of:

a) forming a generally tubular article of polymeric material;

b) radially expanding the article to produce an expanded diameter article; and then,

c) annealing the expanded diameter article to shrink its diameter to a reduced diameter,

wherein the steps a) - c) are all performed prior to deployment of the tubular article in a body, and wherein at least one time steps b) and c) are repeated in sequence on said tubular article.

Claim 16. A medical device adapted for body lumen navigation and/or treatment produced by the process of claim 15.

Claim 17. A process comprising the steps of:

a) forming a generally tubular article of polymeric material;

b) radially expanding the article to produce an expanded diameter article; and then,

c) annealing the expanded diameter article to shrink its diameter to a reduced diameter,

wherein the steps a) - c) are all performed prior to deployment of the tubular article in a body, and wherein the polymer material is a biodegradable polymer.

Claim 18. A process as in claim 17 wherein at least one time steps b) and c) are repeated in sequence on said tubular article.

Claim 19. A process as in claim 17 wherein the polymer material is selected from the group consisting of poly(alpha-hydroxy acid), polylactic acid-polyethylene oxide copolymers; modified cellulose; collagen or other connective proteins; adhesive proteins; hyaluronic acid; polyanhydrides; polyphosphoesters; poly(amino acids); copolymers thereof; and mixtures of any of said materials.

Claim 20. A medical device adapted for body lumen navigation and/or treatment produced by the process of claim 17.

Claim 21. A process comprising the steps of:

a) forming a tube of polymeric material;

b) radially expanding the tube to produce an expanded diameter tube;

c) annealing the expanded diameter tube to shrink its diameter to a reduced diameter;

and subsequently

d) forming a stent from the annealed tube,

wherein the steps a) - d) are all performed prior to deployment of the stent in a body.

Claim 22. A process as in claim 21 wherein the steps b) and c) are repeated at least once on said tube before step d) is performed.

Claim 23. A process as in claim 21 wherein in step d) the stent is formed by machining or etching the reduced diameter tube obtained from step c).

Claim 24. A process as in claim 1 wherein in step a) a pattern of perforations is provided in the tube wall.

Claim 26. A process comprising the steps of:

a) forming a generally tubular article;

b) radially expanding the tubular article to produce an expanded diameter tubular article; and

c) annealing the expanded diameter tubular article to shrink its diameter to a reduced diameter,

the process further comprising

d) forming the tubular article as a stent with a pattern of perforations therein.

Claim 27. A process as in claim 26 wherein the tubular article formed with said pattern of perforations before said radially expanding step b).

Claim 28. A process as in claim 26 wherein the tubular article formed with said pattern of perforations after said annealing step c).

Claim 29. A process as in claim 26 further comprising at least one time repeating steps b) and c) on said tubular article.

Claim 30. A process as in claim 26 wherein the tubular article is formed of thermoplastic polymer material.

Claim 31. A process as in claim 30 wherein the step b) is performed at a temperature below the glass transition temperature of the polymer material.

Claim 32. A process as in claim 26 wherein the tubular article is made of biodegradable polymer material.

(ix) Evidence Appendix

None.

(x) Related Proceedings Appendix

None.